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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,671	06/27/2003	Michael J. Pugia	017191.0033 (MSA-3452)	5201

7590 11/02/2006

Bayer Healthcare LLC
511 Benedict Avenue
Tarrytown, NY 10591

EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,671

Applicant(s)

PUGIA ET AL.

Examiner

Brian J. Sines

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the recited enclosed unidirectional capillary passageway and the enclosed inlet chamber of the microfluidic device must be shown and labeled or the feature(s) canceled from the claim(s). With respect to claim 1, in part c, the device structure comprising the enclosed inlet chamber (reagent area 44?) in fluid communication *at one side thereof* with the enclosed unidirectional capillary passageway of (b) (inlet passageway 42?) does not appear to be clearly shown (see Applicant's figures 1a, 1b, and in particular, 2, 3a, 3b, and 3c). The figures must illustrate the device structural configuration as recited in the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

Art Unit: 1743

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 4 and 6 are provisionally rejected on the ground of nonstatutory double patenting over claims 1, 4 – 6 and 8 of copending Application No. 10/608,400. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Claim Rejections - 35 USC § 102

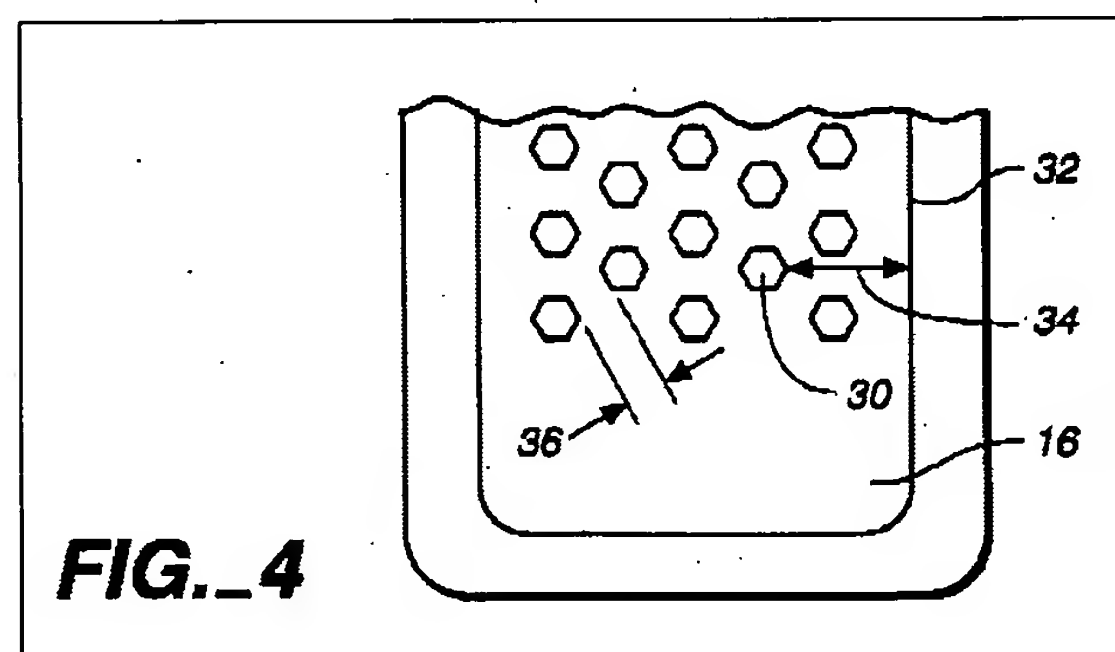
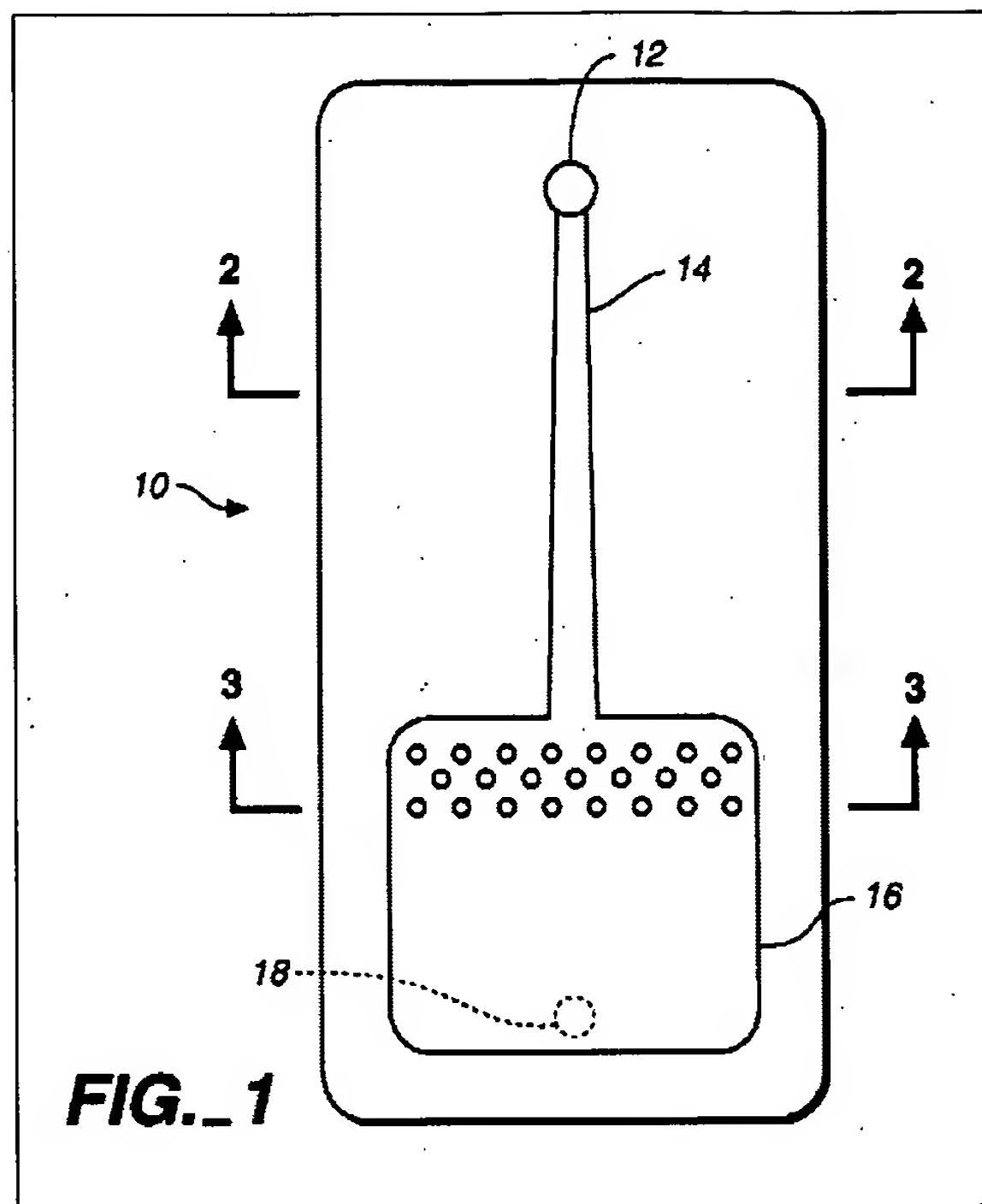
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Buechler (U.S. Pat. No. 6,113,855 A).

Regarding claim 1, Buechler anticipates a microfluidic device comprising: an inlet port 12; an enclosed capillary passageway 14 in fluid communication with the inlet port 12; an enclosed inlet chamber (e.g., distal region 16) comprising an array of post structures (i.e., capillarity-inducing structures 30); and a vent structure (i.e., escape port 18) (see col. 5, line 21 – col. 7, line 43; figures 1 & 4). As shown in figure 1, the enclosed inlet chamber 16 is in fluid communication at one side or end side thereof with the enclosed capillary passageway 14. In addition, as shown in figure 1, the vent passageway 18 is positioned at a top side of the enclosed inlet chamber opposite the entry of the capillary passageway 14 into the enclosed inlet chamber 16.



Regarding claim 8, Buechler anticipates that the inlet chamber 16 containing the assay volume comprises a reagent (e.g., surface bound reactants comprising solid phase bound antibodies which react with sample antigen) (see, e.g., col. 4, lines 42 – 67; col. 5, line 54 – col. 6, line 5). Claim 8 does not specifically recite that the reagents are covalently bound or immobilized within the inlet chamber. This claim does not exclude the interpretation that fluid reagents can be utilized with the disclosed device.

Art Unit: 1743

Furthermore, with regards to claim 8, the recitation that the inlet chamber contains a reagent and/or filter can be considered a statement of intended use, which does not further delineate the structure of the claimed apparatus from that of the prior art. The Court has held that “[e]xpressions relating the apparatus contents thereof during an intended use operation are of no significance in determining the patentability of the apparatus claim.” See *Ex parte Thilbault*, 164 USPQ 666, 667 Bd. App. 1969). Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. Process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (see MPEP § 2114).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

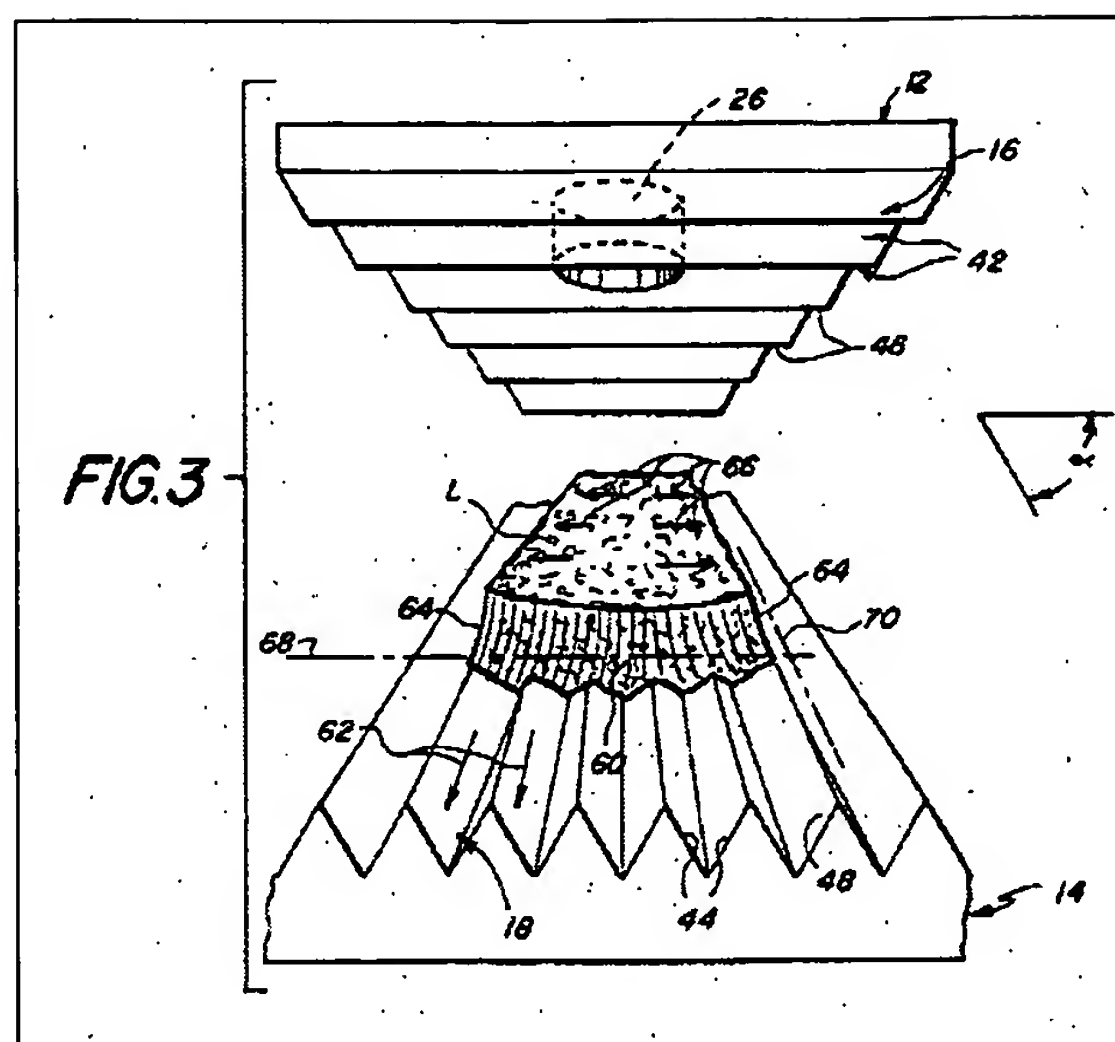
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler in view of Columbus (U.S. Pat. No. 4,233,029).

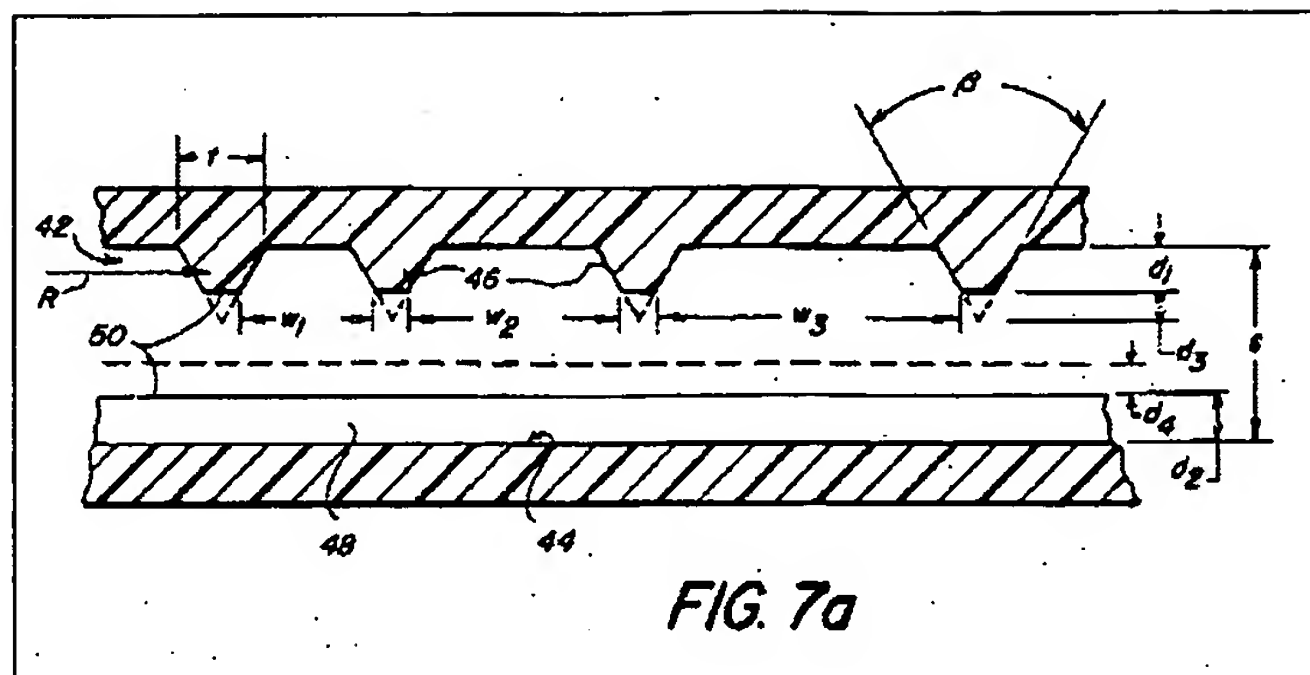
Regarding claim 2, Beuchler does not specifically teach the incorporation of at least one groove structure extending across the inlet chamber 16.

Columbus teaches the use of groove structures (e.g., 42 & 44) for facilitating uniform fluid flow within microfluidic devices (see, e.g., col. 5, lines 1 – 55; figure 3).



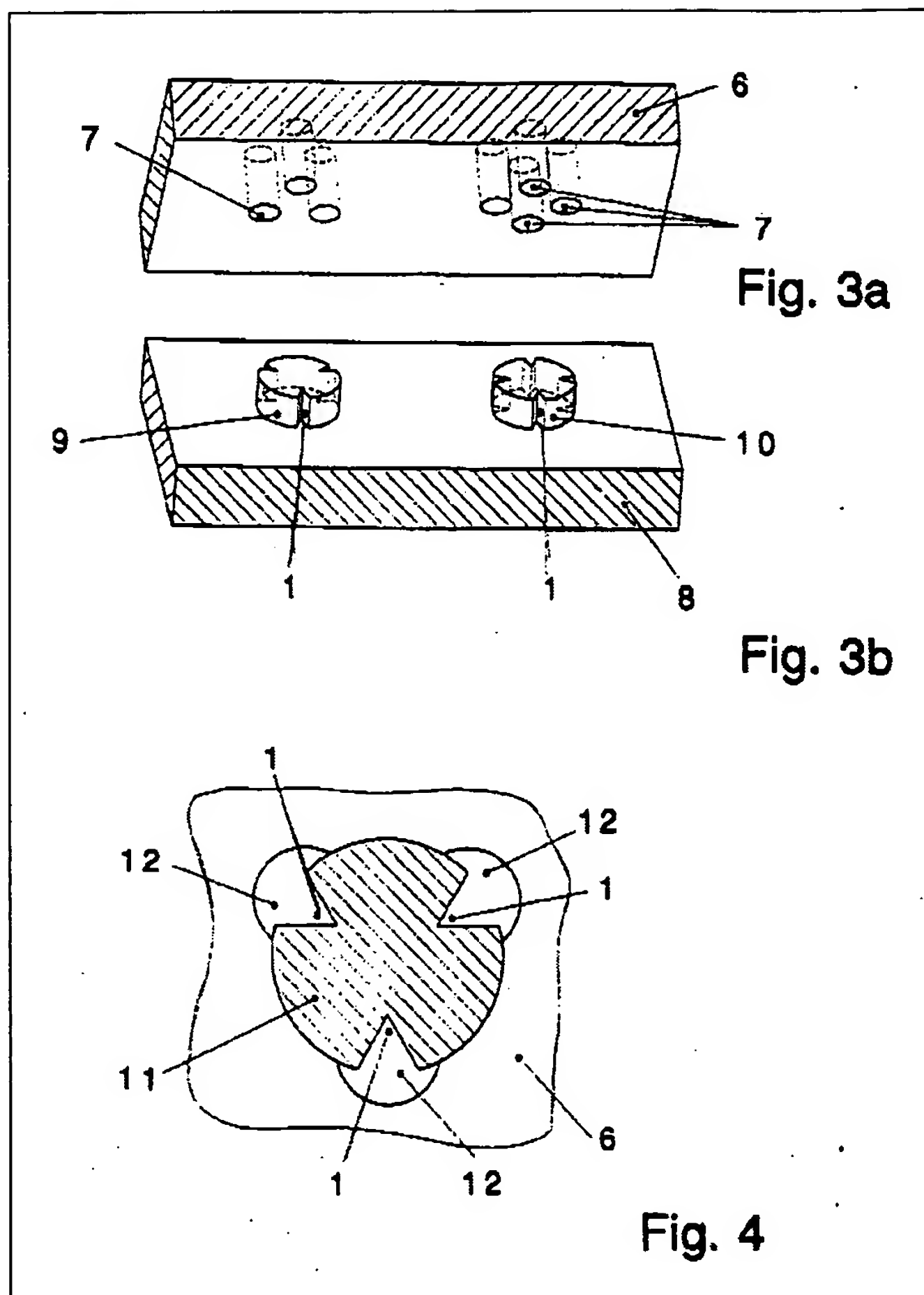
Hence, as shown by Columbus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a groove structure with an analytical microfluidic device for facilitating uniform sample fluid introduction into the device for processing and analysis (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a groove structure as claimed with the disclosed microfluidic device.

Regarding claim 3, as shown in figure 7a, Columbus further teaches the incorporation of weir structures (e.g., truncated ridges 46) within the device (see, e.g., col. 8, lines 1 – 51). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a weir structure as claimed for facilitating effective sample fluid flow with the disclosed microfluidic device.



2. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler and Columbus, and further in view of Peters (U.S. Pat. No. 6,296,126 B1).

Regarding claims 4 and 6, Buechler and Columbus are silent to the specific teaching of incorporating wedge-shaped cut-out structures with either a groove or weir structure within the disclosed microfluidic device. As shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (post or columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).



As evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of wedge-shaped cut-out structures within a microfluidic apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within a microfluidic apparatus for facilitating effective fluid control (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of

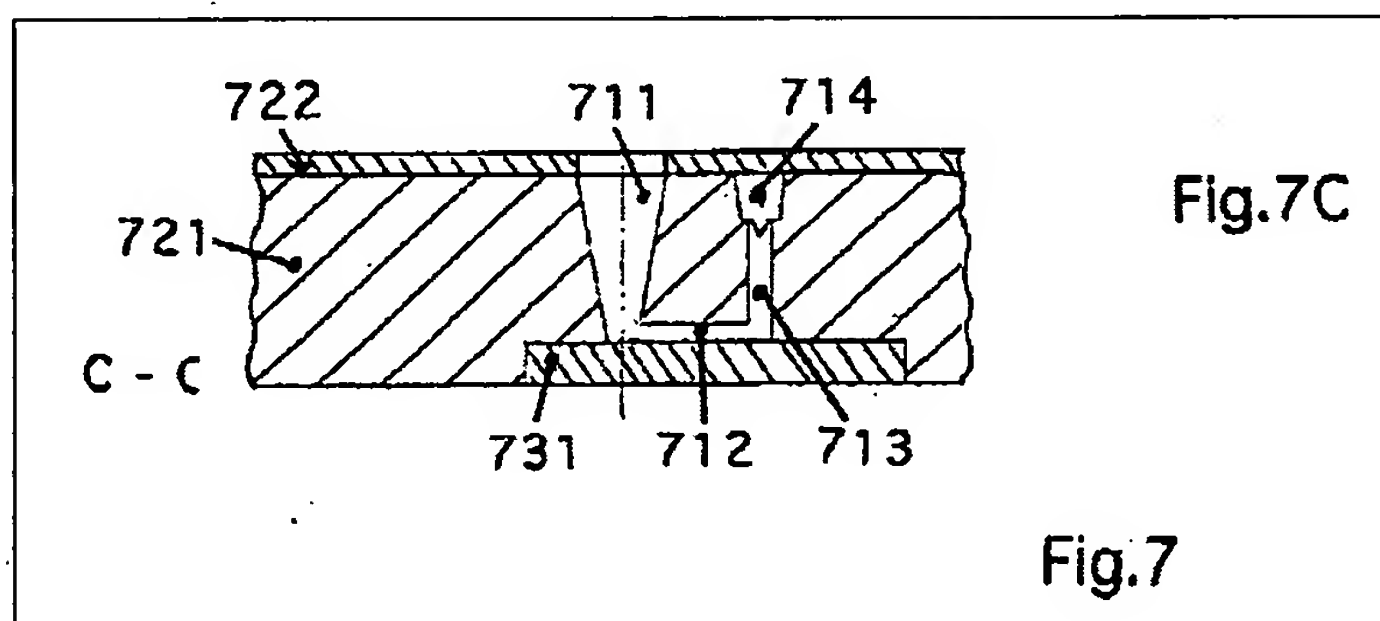
Art Unit: 1743

wedge-shaped cut-out structures as claimed with the disclosed microfluidic device in order to provide an effective for effective sample fluid control within the microfluidic apparatus.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler in view of Wyzgol et al. (U.S. Pat. No. 6,776,965 B2) (hereinafter "Wyzgol").

Regarding claim 7, Buechler does not specifically teach that the inlet port is tapered to engage the corresponding shape of a pipette for depositing a sample to be analyzed.

Wyzgol teaches a similar analytical microfluidic device comprising a tapered, funnel-shaped inlet port 711 designed for taking up the tip of a pipette for facilitating sample introduction into the device (see, e.g., col. 8, lines 30 – 37; figure 7 (7C)).



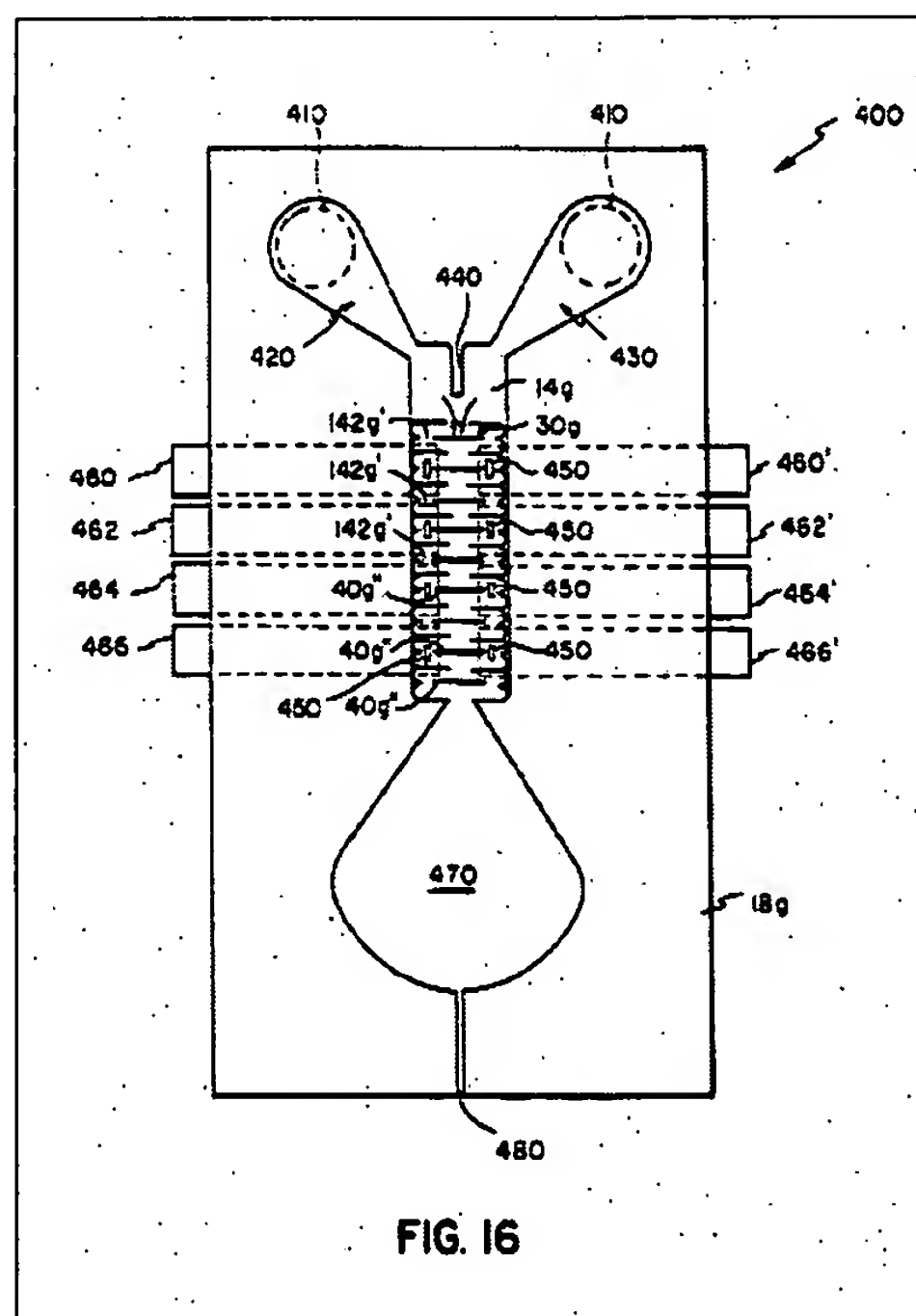
Hence, as shown by Wyzgol, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a tapered inlet port with an analytical microfluidic device for facilitating sample fluid introduction into the device for processing and analysis (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a tapered inlet port as claimed with the disclosed microfluidic device.

Art Unit: 1743

4. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler in view of Columbus (U.S. Pat. No. 4,618,476) (hereinafter "Columbus '476").

Regarding claim 9, Beuchler does not specifically teach the incorporation of an overflow chamber.

Columbus '476 teaches the incorporation of an overflow chamber 470 within a microfluidic device to facilitate effective sample fluid introduction and subsequent processing (see figure 16). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an overflow chamber within the disclosed microfluidic device to facilitate effective sample fluid introduction and subsequent processing.



Regarding claim 10, the recitation that the overflow chamber contains an indicator to detect the presence of excess sample is considered a statement of intended use, which does not further delineate the structure of the claimed apparatus from that of the prior art. The Court has

Art Unit: 1743

held that “[e]xpressions relating the apparatus contents thereof during an intended use operation are of no significance in determining the patentability of the apparatus claim.” See *Ex parte Thilbault*, 164 USPQ 666, 667 Bd. App. 1969). Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. Process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (see MPEP § 2114).

Response to Arguments

Applicant's arguments with respect to the present claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1743

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

